**REMARKS**

Claims 5, 7, 10-12, 16-19, 21-23, 27 and 28 were pending in this application. Claims 5, 7, 10-12, 16-19, 21-23, 27 and 28 have been rejected. Claims 19, 27 and 28 have been amended and new claim 29 has been added. Support for the amendments is provided in the specification at page 7, line 15, and page 10, lines 16-22. No new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

**I. Rejection under 35 U.S.C. § 112, second paragraph**

Claim 19 has been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for lacking antecedent basis for N-vinyl-2-pyrrolidone.

Accordingly, to further prosecution of this case Applicants have amended claim 19 so that it no longer recites, "N-vinyl-2-pyrrolidone".

Withdrawal of this rejection is therefore respectfully requested.

**II. Rejections under 35 U.S.C. § 103**

Claims 5, 7, 10-12, 16-19, 21-23, 27 and 28 have been rejected under 35 U.S.C. § 103 as being unpatentable over Int'l Application Pub. No. WO 99/02141 to Kamiyama

("Kamiyama") in view of U.S. Patent 5,532,373 issued to Matsumoto et al. ("Matsumoto").

Applicants respectfully traverse this rejection.

Applicants respectfully submit that neither Kamiyama nor Matsumoto disclose, suggest, or predict either of the processes recited in independent claims 27 and 28. Applicants respectfully traverse the rejection because (1) Kamiyama and Matsumoto each fail to dissolve a drug and a polymer in a lower alcohol solution before "adding a [crosslinking agent to the same solution].. thereby to form the medical patch" (claim 27); (2) Kamiyama and Matsumoto each fail to dissolve a drug and crosslinker in a lower alcohol solution before "adding a [polymer to the same solution].. thereby to form the medical patch" (claim 28); and (3) Matsumoto is too far removed from the knowledge of one having ordinary skill in the art, and too lacking in any design incentives, to be combined with Kamiyama.

The case law is clear; to establish obviousness, the prior art references must teach or suggest all of the particular limitations of the claims. *In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970); *In re Royka*, 490 F.2d 981 (CCPA 1974). Kamiyama and Matsumoto, however, each fail to

disclose at least one of the claimed limitations in both of claims 27 and 28.

Regarding claim 27, Kamiyama fails to teach dissolution of a drug and a polymer in a lower alcohol solution before "adding a [crosslinking agent to the same solution]… thereby to form the medical patch". Although peroxide is added in an initial step, Kamiyama does not recite the addition of any crosslinker after the drug and polymer are dissolved together in an alcohol solution, which is required in the process of claim 27. Kamiyama also fails to teach "dissolving in a lower alcohol… a polymer" as recited in claim 27. Although Kamiyama may show dissolving a drug in methanol, *see* Kamiyama, Example 1, this reference does not teach "dissolving in a lower alcohol… a polymer". Kamiyama instead shows dissolution of a polymer only in ethyl acetate or toluene, not a lower alcohol. *Id.*, at Table 6.

Moreover, a reasonably broad interpretation of "dissolving" does not include mere mixing or adding. Both soft and hard co-polymeric constituents of Kamiyama are first dissolved in non-alcoholic solutions before they are mixed with any other substance. See specifically page 21, lines 6 and 7 of Kamiyama which states "In all of the above cases, the solvents used were toluene… and ethyl acetate… in

all cases." Thus, the polymers of Kamiyama are clearly not dissolved in a lower alcohol as required in the instant claimed invention.

Matsumoto likewise fails to dissolve a drug and a polymer in a lower alcohol solution before "adding [a crosslinking agent to the same solution]… thereby to form the medical patch." Matsumoto does not add a crosslinker (allegedly, boric acid) to a dye/polymer lower alcohol solution, at least not until after complete formation of all products made by Matsumoto's processes. Matsumoto's various processes never add boric acid to the dye/polymer solution, which is formed and protected from such addition by its emulsification (in droplets) or microencapsulation (*see* col. 27, line 28 and col. 34, line 66; col. 26, line 66 through col. 29, line 23; col. 24, lines 52-56 of Matsumoto). These emulsification and microencapsulation steps, which are part of forming the product (whether it be a photopolymerizable compound, a light sensitive element, an image receiver element, an image forming element (with binder), an unexposed layer, or otherwise), preclude Matsumoto from performing this limitation of claim 27.

Because all of Matsumoto's dye/polymer solutions are either microencapsulated or emulsified, moreover, they are

thereby protected from interaction with boric acid at least until use. In fact, any and all subsequent boric acid addition to the emulsified or microencapsulated post-production dye/polymer could occur only during use, that is after all of Matsumoto's various product formation steps are completed. Any suggestion of an "inherent" release of the first microencapsulated dye/polymer solution, which is the only way boric acid could even possibly be added to such solution, necessarily occurs, if ever, during use of Matsumoto's image forming material, *i.e.*, when exposed to light to form an image, which is well-outside all processing steps that form any of the various products in Matsumoto. For this reason Matsumoto does not teach adding boric acid to a drug/polymer alcohol solution "… thereby to form the medical patch".

Kamiyama and Matsumoto also each fail to disclose at least one of the claim limitations of claim 28. In particular, Kamiyama fails to teach dissolution of the drug and a crosslinker in a solution before "adding [a polymer to the same solution]…thereby to form the medical patch" (claim 28). Kamiyama does not recite the addition of any polymer to the drug solution <u>after</u> the drug is dissolved, which is required by claim 28.

Matsumoto likewise fails to teach dissolving a dye and boric acid in a solution before "adding [a polymer to the same solution]…thereby to form the medical patch" (claim 28). Matsumoto does not ever add a polymer to a dye/boric acid alcohol solution because (1) no such medical patch is created by Matsumoto and (2) as described above, Matsumoto does not describe or allow for any production methods in which a dye is dissolved in the same solution as boric acid to form a product.

Further, notwithstanding the Supreme Court's recent *KSR* decision, Applicants believe the combination of teachings of Kamiyama with the teachings of Matsumoto is improper. In particular, Applicants respectfully submit that Matsumoto is not properly cited as analogous art. The Court in *KSR* stressed application of the *Graham* test, in which the level of ordinary skill in the art must be resolved. *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1735 (2007)("KSR"). Under this rubric, it is highly doubtful that one having ordinary skill in the art to which the present invention relates would have any knowledge of Matsumoto, much less specific knowledge of Matsumoto's teachings, because they are not reasonably pertinent to the problem(s) presented in the subject matter of the present invention.

Nearly 30 years ago, the CAFC's predecessor recognized that no person having ordinary skill in the art could possibly be presumed to know every prior art reference in every field of endeavor. *In re Wood*, 599 F.2d 1032, 1036 (CCPA 1979). Thus, in cases where a reference (such as Matsumoto) is not in the same field of endeavor as a claimed invention (here a process for making a medical patch), to be considered within the knowledge of one having ordinary skill in the art, it must be "reasonably pertinent to the problem with which the inventor was concerned[.]" *Id.*; *see also, e.g.*, *In re Clay*, 966 F.2d 656, 659 (Fed. Cir. 1992); *In re Oetiker*, 977 F.2d 1443 (Fed. Cir. 1992); *Wang Laboratories, Inc. v. Toshiba Corp.*, 993 F.2d 858 (Fed. Cir. 1993); and *In re Paulsen*, 30 F.3rd 1475 (Fed. Cir. 1994).

As suggested by its implicit endorsement by the Supreme Court in *KSR,* and as held in subsequent CAFC decisions, a determination of analogous art by this same standard is still good law. In *KSR* the Supreme Court lauded the CAFC's *In re Khan* decision, in which the CAFC stated as follows:

> Although our predecessor court was the first to articulate the motivation-suggestion-teaching test, a related test—the "analogous art" test—has long been part of the primary *Graham* analysis articulated by the Supreme Court. *See Dann*, 425 U.S. at 227-29; *Graham*, 383 U.S. at 35. The analogous-art test requires that the Board show that a reference is either in the field of the

> applicant's endeavor or is reasonably pertinent to the problem with which the inventor was concerned in order to rely on that reference as a basis for rejection. *In re Oetiker*, 977 F.2d 1443, 1447 (Fed. Cir. 1992). References are selected as being reasonably pertinent to the problem based on the judgment of a person having ordinary skill in the art. *Id.* ("[I]t is necessary to consider 'the reality of the circumstances,'—in other words, common sense—in deciding in which fields a person of ordinary skill would reasonably be expected to look for a solution to the problem facing the inventor." (*quoting*, *In re Wood*, 599 F.2d 1032, 1036 (C.C.P.A. 1979))). We have explained that this test begins [but is separate from] the inquiry into whether a skilled artisan would have been motivated to combine references by defining the prior art relevant for the obviousness determination, and that it is meant to defend against hindsight. *See id.; In re Clay*, 966 F.2d 656, 659-60 (Fed. Cir. 1992).

*In re Kahn*, 441 F. 3d 977, 988 (Fed. Cir. 2006) (*citing*, several Supreme Court cases to support this proposition).

In August of 2007, the CAFC accordingly held:

> "If reasonably pertinent to the problem addressed by Icon, Teague may serve as analogous art. *Paulsen*, 30 F.3d at 1481. "A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem." *In re Clay*, 966 F.2d 656, 659 (Fed. Cir. 1992). In other words, "familiar items may have obvious uses beyond their primary purposes." *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1742 (2007)."

*In re Icon Health and Fitness, Inc.*, No. 2006-1573 (Fed. Cir. Aug. 1, 2007).

Thus, clear from well-established case law is that all references must still be either within an application's field of endeavor or "reasonably related to the particular problem with which the applicant was concerned[.]" *Id.*

Matsumoto does not logically commend itself to the attention of one having ordinary skill in the art of the instant invention, which is directed to a process for making medical patches, not photopolymerizable dye materials. The compositions, processes, and results of Matsumoto are vastly different from the medical patch compositions, processes, and results of the present invention. In particular, Matsumoto almost exclusively concerns light sensitive polymerization compositions, in which a dye bleaching method is used, and their use in various image forming materials. (col. 1, lines 11-33 and col. 3, lines 20-57). These aluminate complexes, dyes and associated polymers are protected by either micro-encapsulation or emulsification, which makes operative polymerization dependant on a light-source. See col. 3, line 65 through col. 29, line 22 of Matsumoto. This is especially true when Matsumoto's image forming materials preferably also contain heat-polymerization inhibitors. (col. 30, line 17). This emulsification or encapsulation runs contrary to the patch

compositions of the instant invention, which instead of isolating a drug, make it readily available for use without light initiation.

Further, the microcapsules typical to Matsumoto are of very specific sizes and preferably respond to changes due to pressures under $10kg/cm^2$, but should be frangible at higher pressures (see col. 28, lines 46-57 of Matsumoto), which has little bearing on the simple adhesive requirement needed to attach a medical patch to skin or another body part.

The requirement for light-activation in the photographic arts also tends to limit the design options and considerations available as compared with the options otherwise available and suitable for medical patches. This constraint rules out, for example, the use of any adhesive polymers that thermally crosslink such as in the instant invention. Being light-activated also appears to require available matrix polymer materials to be transparent or possibly translucent polymers, which unduly limits the choices available for Applicant's medical adhesive patch.

For someone having ordinary skill in the art of medical patches, the complexities and specific considerations of Matsumoto's photographic-related components are expansive. Matsumoto describes a combination of the highly-complex aluminate complexes, multitudes of possible carcinogenic

dyes, and various emulsion and encapsulation techniques used to make the primary polymerizable composition light sensitive - the resulting light sensitive materials also contain optional oxygen scavengers, color image forming substances (such as dyes, pigments, colorless [thermally activated, pressure activated, or light activated or combined component substances], and combinations thereof), and color developers. All of these and other components are used in conjunction with an image receiving material/element and associated binder(s). Description directed solely to these light sensitive materials and their accompanying optional components requires 26 of Matsumoto's 52 columns of text and graphics.

Matsumoto's image forming materials also optionally contain additional layers not required by a medical drug delivery patch, such as those with variously-hued photobleachable dyes that form superimposed colors, with an additional UV-absorber-containing layer between each one of them (see col. 36, lines 23-37 of Matsumoto). These layers optionally contain still more surfactants for emulsification (to hinder active agent exposure) and to prevent adhesion (see col. 37, lines 40-46 of Matsumoto). By contrast, simpler medical drug delivery patches comprise typically perhaps one layer that is designed to deliver as much

drug/drug content over time as possible, and adhere to a wearer's body without further complication.

Matsumoto's image receiving element, on the other hand, differs substantially from the instant invention because it forms an extra layer and/or represents yet another functional matrix component structurally unnecessary for the drug patch of the instant invention. Clearly the requirements of the devices of Matsumoto dictate a very different set of design considerations unrelated to user conformance, bio-compatibility, hardness and flexibility as in the instant invention.

All in all, of the 52 columns in Matsumoto, only one full, complete column (*i.e.*, column 38) actually describes the process and materials of mixing the various vastly differing components of the image forming material, coating this mixture, and drying it on a substrate. Almost all of the remaining non-cumulative disclosure in Matsumoto describes the photosensitive compositions mentioned above.

Perhaps more importantly, Matsumoto's image receiving element immobilizes the color image forming substance, *i.e.*, the dye, which the Examiner inappropriately relates to a drug. Matsumoto describes the image receiving element as "an element causing coloring of and/or immobilizing the

color image forming substance released from the light-sensitive microcapsules." See col. 29, lines 23-27 of Matsumoto. Along these same lines, Matsumoto's product is improved by limiting the amount of dye that is transferred by "removing unpolymerized portions" presumably to enhance resolution and contrast. See col. 24, lines 58-63 through col. 25, lines 1-3 of Matsumoto.

By contrast, a person having ordinary skill in the art related to the instant invention would very likely not wish to immobilize drug of a medical patch (which would render it useless). If, however, such a person did wish to immobilize a drug, it is very unlikely that he or she would seek to immobilize it so soon after its release. If teachings of Matsumoto were reasonably pertinent to the problems of the instant invention, whether in the same layer or support, Matsumoto's image receiving element would fairly quickly mobilize (not immobilize) any released dyes/drugs.

Thus, Matsumoto's basic light sensitive material and image receiving polymer matrix structure, whether comprised of several or many layers, seeks to hold its active compositions in place within a polymer matrix that resists transfer, elution, or other internal movement within the matrix, so as to provide maximum resolution and contrast. In contrast, the instant invention seeks to obtain

unfettered and unhindered delivery of a drug from its polymer component. The compositions disclosed in Matsumoto thus provide design considerations antithetical to the purposes of, and providing further needless complication to, one considering the composition and process of making a medical patch.

Matsumoto's Examples 1-6, by which the image forming materials spanning a spectrum of image forming applications provided by Matsumoto are made, provide little, if any, assistance to a medical patch researcher who is seeking to make a particular patch for usually a particular drug's delivery according to that drug's bioavailability, effectiveness, dosage and stability requirements. For example, Examples 3 and 4 of Matsumoto disclose 2 and 1 micron layers, each being a coat layer and an over coat layer, which may be suitable for photographic coatings, but are hardly thicknesses suitable for a versatile drug delivery patch. Such a patch would need to have a much thicker layer, of which thickness typically ranges from about 30 to about 300 microns, to contain enough drug for delivery. Applicants respectfully direct the Examiner to teachings of the instant specification on page 20, line 16 wherein a pressure sensitive adhesive layer of 80 microns is described.

Thus, the matrix necessarily required by Matsumoto's image forming materials would add so many considerations and factors that run counter to the considerations inherent to the problems faced when forming a medical patch, that it is hard to imagine that one skilled in the art of medical patches would look to it for any sort of guidance as to materials, processes, or design.

For the above reasons Matsumoto is not reasonably pertinent to the problem(s) addressed by Applicants, and would not have commended itself to the attention of a person having ordinary skill in the arts to which the instant invention relates. It is therefore improperly classified as an analogous reference in this case.

The second reason why it is improper to combine teachings from Kamiyama with teachings of Matsumoto, is because of a failure to provide sufficient design incentives. The Examiner gives the following as reason for replacing Kamiyama's peroxide with Matsumoto's boric acid:

> "In view of such disclosure, it would not be difficult to one of ordinary skill in [the] art to that the material compositions of Matsumoto et al. and Kamiyama are very similar, particularly relating to the use of adhesive film for release of a substance. Therefore when Matsumoto et al. (col. 40-43, examples 3-5) disclose a shorter time required for drying at 100°C for 2 minutes, and at about 50°C for 15 minutes when Boric acid is used, motivated by the expectation of success of reducing drying or curing time of Kamiyama, it would have been obvious… to replace the peroxide

curing system of Kamiyama with boric acid curing system of Matsumoto et al. to obtain [Applicants' claimed invention]"

Applicants respectfully disagree as neither reference indicates a faster drying time when using boric acid, comparative thicknesses actually indicate the opposite, and general design considerations teach away from such combination.

It is first noted that Matsumoto's Examples do not use boric acid. Thus, the Examiner's reliance on these data to show advantages of using boric acid is unwarranted. Further, these data actually tend to teach away from the use of any of Matsumoto's hardeners. To the extent that it is appropriate to compare the very thin films (2 and 1 microns) created by Matsumoto to medical patch coatings, which range from about 30 to about 300 microns, the data in Matsumoto actually indicate slower drying times. Had Kamiyama or other medical patch makers used such thin films, drying times would be exceedingly much lower than those indicated in Kamiyama (or in the general medical patch art) because such a thin film containing such small quantities of coatings would dry much, much faster than all of Matsumoto's exemplary films.

Such thin, small films therefore illustrate how Matsumoto in fact teaches away from its combination with Kamiyama. No versatile medical patch could hold sufficient amounts of a drug in such thin, small films to be of much use for delivering that drug. Thus, Applicants respectfully submit that Matsumoto, Kamiyama and relevant art collectively teach against the existence of any design incentives or market forces which would have prompted adaptation of Kamiyama as claimed.

More generally, the above-mentioned reasons that set forth the general inconsistencies and incompatibilities of the photopolymerization compositions to medical patches further dictate that Applicants' claimed invention is not obvious over Kamiyama in view of Matsumoto. Because someone having ordinary skill in the art would not know, and in fact would be directed away from, the use of boric acid in place of peroxide also thereby defeats any showing that the difference between using peroxide and boric acid was a known variation or a known principle.

Finally, a person having ordinary skill in the art could not have implemented the claimed variation simply because such use would have been too far outside of his or her knowledge base.

Thus, Kamiyama and Matsumoto each (1) fail to dissolve a drug and crosslinker in a lower alcohol before adding the polymer (claim 27) to form a medical patch, and (2) fail to dissolve a drug and polymer in a lower alcohol before adding the crosslinker (claim 28) to form a medical patch. It is furthermore inappropriate to combine Matsumoto with Kamiyama to make the claimed invention.

Withdrawal of this rejection under 35 U.S.C. 103(a) is therefore respectfully requested.

**III. Conclusion**

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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Date: **January 24, 2008**

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